No. 95-2018

Supreme Court, U.S.
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In The

Supreme Court of the United States

October Term, 1995

HOWMEDICA, INC.,

Petitioner,

vs.

MARILYN HAUDRICH, as Executor and Sole Legatee of Donald Haudrich, Deceased,

Respondent.

On Petition for Writ of Certiorari to the Supreme Court of the State of Illinois

RESPONDENT'S BRIEF IN OPPOSITION

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TABLE OF CONTENTS

	Page
Additional Background and Facts	1
Reasons for Denying the Writ	2
I. Congress Did Not Intend To Preempt The Causes Of Action Pleaded In This Case.	2
II. Any Preemption Defense Under MDA (If It Exists) Is Waivable, And Defendant Did Waive It By Failing To Raise It As An Affirmative Defense In The Trial Court.	4
Conclusion	6

TABLE OF CITATIONS

Cases Cited:

International Longshoreman's Ass'n v. Davis, 476 U.S. 380 (1986) 4

Medtronics v. Lohr, #95-754 and 95-886, WL 345805 ..... 2, 3, 4, 5

Violette v. Smith & Nephew Dyonics, Inc., 62 F.3d 8 (1st Cir. 1995) 4

Statute Cited:

21 U.S.C. § 360 *et seq.* 1

ADDITIONAL BACKGROUND AND FACTS

In the course of trial Howmedica's officer in charge of FDA compliance (a lawyer named Charles Lawyer), was cross-examined in respondent/plaintiff's case in chief. (Tr. pp. 269-316). Howmedica produced about 100 adverse incident reports which were addressed on this examination. *Id.* The system to track such incidents had only been in place for about two years prior to trial. *Id.* These reports were redacted to remove the patients' names and other personal data, but they concerned plastic failure, which was the alleged defect in this case. *Id.* Lawyer could not identify the report on the respondent's decedent or another client of respondent's trial counsel. *Id.* Lawyer suggested these may be the only two oversights. *Id.*

Lawyer also testified about the requirement to provide Medical Device Reports to the FDA within five days of notice to the manufacturer by a physician of a serious injury caused by the device. *Id.* Nonetheless, he had not submitted such a report to the FDA on this case. *Id.* Lawyer explained he never read the patient's physician's trial deposition in this case taken in March, 1991 (wherein such information was contained). He testified Howmedica had never concluded a device was at fault for a reported failure. *Id.* Those conclusions were made although in many instances the devices were not retrieved, medical records were not obtained and no other investigation was done to determine the reason for the failure. *Id.*

Despite the presence at trial of this employee, petitioner did not present evidence about the scheme of the Medical Device Amendments 21 U.S.C. § 360 *et seq.* (MDA) to classify devices, the process of FDA approval or the classification of the PCA Knee Device under the MDA which was exhaustively described in petitioner's brief , pages three to six.

Respondent's expert, Roy Bloebaum, Phd., was highly qualified in the field of failure analysis of prosthetic devices. (Tr. pp. 73-118, 185-191). He was a full professor at the University of Utah School of Medicine, Division of Orthopedic Surgery and was also employed at the Bone and Joint Research Lab of the VA Medical Center, Salt Lake City. *Id.* Independent of his participation in this case, he had performed failure analysis of the PCA type knee in the course of his work at the VA Center. *Id.* Among other criticisms of the device at issue he testified to a reasonable degree of scientific certainty that the product was defective and unreasonably dangerous because the polyethylene plastic portion was too thin and such defect contributed to the premature failure of the device. *Id.*

Petitioner asserted a preemption defense for *the first time* before the Fifth District Appellate Court of Illinois. Attached to their brief then was the C.F.R. and Federal Register excerpts which now appear in petitioner's brief (App. E, pp. 63a-66a). Petitioner sought judicial notice of those documents and if acceptable, they would be the only material of record demonstrating the classification of this device.

REASONS FOR DENYING THE WRIT

I.

CONGRESS DID NOT INTEND TO PREEMPT THE CAUSES OF ACTION PLEADED IN THIS CASE.

This case is resolved by the result in *Medtronics v. Lohr,* #95-754 and 95-886, WL 345805. In their brief petitioner has suggested facts and inferences about the status of the device that inaccurately color the merits of the defense asserted herein. Most assuredly to gain a better stand they incorrectly posture the preemption claim as one concerning a Class III device with

premarket approval, and/or an investigational device exemption (IDE). Accepting for the sake of argument that the court can take judicial notice of the evidence in the C.F.R. and Federal Register that premarket approval was granted for the device, it was not conferred until 1988, about three years after the device was implanted. Moreover, while petitioner's refer to an IDE for this device they do not mention there was no evidence the surgeon who implanted this device was part of any FDA approved test of the product. Most importantly, there is *nothing* in the trial record of this case documenting acceptance of the product into the IDE program. As such there is no record citation to the claim in petitioner's brief about an IDE for this device (Pet. Brief, p. 6) and respondent has never admitted those facts. What petitioner seeks is to have this court apply premarket approval retroactively, or find an investigational device exemption existed where there is no evidence it was authorized.

Perhaps the fatal flaw in Howmedica's preemption argument is that while they argue Congress clearly intended to preempt the claims asserted and provide this extraordinary, pervasive defense their own inaction defies such characterization. If the intent was so patent, why didn't this sophisticated manufacturer, (who had an attorney employed as the FDCA regulatory compliance manager), fail to raise the defense in the trial court over 15 years after the MDA's enactment?

Any preemption analysis should be made on the basis of the status of the device in September, 1985 when it was implanted or earlier when it was sold. By petitioner's own facts, in 1985 the prosthesis was a Class II device with marketing approval through the 510k process. (Pet. Brief, p. 6). As such, *Medtronics v. Lohr,* WL 345805, controls the result herein and there is no preemption of any of the claims.

II.

ANY PREEMPTION DEFENSE UNDER MDA (IF IT EXISTS) IS WAIVABLE, AND DEFENDANT DID WAIVE IT BY FAILING TO RAISE IT AS AN AFFIRMATIVE DEFENSE IN THE TRIAL COURT.

The Illinois Supreme Court correctly analyzed the case under *International Longshoreman's Ass'n v. Davis,* 476 U.S. 380 (1986), and determined that if there was a preemption defense, it was waived by defendant herein. Petitioner erroneously attempts to analogize the FDA to the NLRB. *Davis* instructs that for a defense to constitute subject matter jurisdiction it must be a matter of a forum question rather than a choice of law. *Id.* In this case the Illinois Supreme Court correctly determined that unlike the NLRB, the FDA was not an alternative forum for dispute resolution and the question was whose law controlled. (Pet. Brief, App. A). The Illinois Court's opinion is completely consistent with the opinion in *Violette v. Smith & Nephew Dyonics, Inc.*, 62 F.3d 8 (1st Cir. 1995) (holding MDA preemption defense could be waived), and other federal courts analyzing the nature of other statutes providing a defense of federal preemption. (Ill. Sup. Ct. Op. and cases cited therein, at Pet. Brief, App. A., p. 11a).

While the waiver issue was not specifically before the court in *Medtronics v. Lohr,* WL 345805, by inference it is resolved by the result therein. For petitioner to be correct in their assertion that the Illinois Court lacked subject matter jurisdiction there could be no private enforcement of FDCA requirements. A consensus of the Court in *Medtronics* found if a product did not comply with an FDCA requirement no conflict would arise from a state civil action brought to enforce such requirement. *Id.* Accordingly, the state court in Illinois had jurisdiction over the

matter of whether a conflict existed, and under Illinois rules the defense should have been presented for consideration in the trial court. (Pet. Brief, App. A).

In that the matter was not raised in the trial court proceedings very little information is in the record regarding the FDA's actions on this device. What *is* known is Howmedica only had a system in place as of about 1989 to monitor complaints about the device. A further questionable practice is suggested by the fact that despite sworn testimony of a treating physician about a serious injury caused by the device, no Medical Device Report was made to the FDA of that opinion. Finally a question of compliance is raised concerning why this device was implanted without bone cement three years before it was approved for use in that manner.

As well described in the Illinois Supreme Court's decision in this case, (Pet. Brief, App. A), waiver is an equitable doctrine. It abides by a simple principle of fair play: if one party fails to raise an issue they cannot later cry foul, because by their own inaction or trial tactics they denied the opposing party the opportunity to substantively respond. *Id. Medtronic v. Lohr* confirms respondent was prejudiced by petitioner's failure to timely raise the defense because serious questions of compliance with FDA regulations are apparent. Respondent was denied any opportunity to further discover or plead any matters concerning compliance with the regulations.

CONCLUSION

For the reasons stated herein and those contained in the lower courts' opinions, respondent asks this court to deny the petition for writ of certiorari.

Respectfully submitted,

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